

REMARKS

1. Applicant wishes to thank Examiner for the indication that claim 13 contains allowable subject matter.
2. Applicant notes that no grounds of rejection were stated for claims 3, 5 and 7. Applicant has taken this as an indication that these claims are also allowable.
3. Claims 1, 4, 6, 9, 12 and 19 were rejected under 35 USC 103(a) as being unpatentable over Paton et al. (US 4,120,291) in view of Hayakawa et al. (US 5,575,291).

Applicant notes that claim 11 is discussed under this section of the Office Action, but is not explicitly rejected. If this was done in error, Examiner is invited to correct this omission in a subsequent non-final Office Action.

4. Applicant respectfully traverses the rejection of claims 1, 4, 6, 9, 12 and 19 under 35 USC 103(a). Examiner states that it would be obvious to substitute the gel material of Hayakawa for the flexible plastic membrane 16 of Paton to arrive at Applicant's claimed invention. However, Applicant submits that such a substitution would not be obvious or even desirable to one of ordinary skill in the art.

One of ordinary skill in the art will recognize that the flexible plastic membrane 16 of Paton must possess a certain minimum tensile strength in order to effectively contain the fluid F within the fluid coupling. On the other hand, the entire point of the Hayakawa patent is to provide an ultrasonic coupling made of a gel material that is so flexible that it will readily deform to fit the steep undulations of a body surface, even with very little force applied. This object of the invention is repeatedly emphasized in the Summary of the Invention and throughout the patent specification. The gel material, as it is described, is barely solid. In fact, it cannot even support its own weight without water oozing out of the gel material. (See column 8, line 66 - column 8, line 9.) This characteristic of the gel material makes it unsuitable for use as a substitute for the

flexible plastic membrane 16 of Paton. This is akin to attempting to make a window to hold back fluid out of dessert gelatin. The chances of success in this endeavor are slim to none. Applicant directs Examiner's attention to MPEP § 2143.02, which states that a reasonable expectation of success is required for a finding of obviousness:

2143.02 Reasonable Expectation of Success Is Required [R-6]

>A rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art. KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007); Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

Furthermore, it would entail a change in the working principles of the Hayakawa invention to use the gel material as a window to enclose a fluid coupling material for ultrasonic imaging. In Hayakawa, the gel material itself is the coupling material, no coupling fluid is required, therefore there would be no motivation to modify the reference as suggested by the Examiner. See 2143.01(VI):

VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

Thus applicant submits that it would not be obvious to combine the Paton and Hayakawa references as suggested by the Examiner and, even if combined, the combination would not result in Applicant's claimed invention because the suggested combination would be nonfunctional. Examiner is respectfully requested to withdraw the rejection of claims 1, 4, 6, 9, 12 and 19.

Regarding claim 9, Examiner states that Paton discloses "means for adjusting a distance between said scan window and the transducer to allow adjustment of a position of said scan window with respect to a focus of the transducer." However, Applicant submits that this is erroneous. Applicant finds that the section of Paton cited by Examiner (column 1, lines 11-18) is irrelevant to this claim limitation:

In general the devices used have comprised a probe which is moved or scanned manually over a patient's body. In recent times it has been realised that it would provide better results if the scanning could be automated and made more predictable and accurate. This is particularly important where fast scanning is required to provide real-time ultrasonic "pictures" of moving organs such as the heart.

On the other hand, column 1, lines 11-18 of Paton directly contradict Examiner's statement:

It is to be noted that the probe 3 is arranged to oscillate about the centre point of the face 6. This is primarily determined by the arcuate track provided by the guide grooves 10 whose curvature is centred on the centre point of the face 6. To ensure clearance between the crank 12 and the guide 40, the latter is provided with an arcuate upper surface whose curvature corresponds to that of the grooves 10 in order that the ball race runs in the guide 40 at a substantially constant depth (the centre of the ball race is substantially equidistant from the centre point of the face 6 at all times).

Contrary to Examiner's assertions, the configuration of the oscillating mechanism ensures that the face 6 of the ultrasonic transducer probe 3 remains a constant distance from the membrane 16 at all times. No means for adjusting this distance is disclosed. Examiner is respectfully requested to withdraw the rejection of claim 9.

Regarding claim 11, Examiner states "Hayakawa teaches fitting the scan window to fit the profile of a body surface even with steep undulations." However, this teaching does not anticipate the claim limitation "wherein a distal surface of said scan window has a concave curve to approximate a curvature of an eye." The gel material of the ultrasonic coupling in Hayakawa conforms to the body surface by deforming. This is a different operating principle than having a preformed concave curve that approximately matches

the curvature of the patient's eye. (See 2143.01(VI), cited above.) Furthermore, it would not be obvious to modify the ultrasonic coupling of Hayakawa to have a preformed curvature because it would be totally unnecessary. As pointed out by Examiner, the soft, flexible gel material deforms to fit virtually any body surface with very little force applied, therefore there is no need to make the ultrasonic coupling with a concave curve to approximate a curvature of an eye. Thus, the features of claim 11 would not be obvious to one of ordinary skill in the art from the combined teachings of Paton and Hayakawa. Examiner is respectfully requested to withdraw the rejection of claim 11.

Regarding claim 12, Examiner states "Paton teaches wherein the reservoir comprises a plurality of separate pieces between which the scan window is mechanically secured (Col. 3, Line 1-2)." However, Applicant submits that this is erroneous. Applicant finds that the section of Paton cited by Examiner is irrelevant to this claim limitation:

...indicated at 101. The probe 3 is in any case removable from the carriage 4 as mentioned above.

The carriage 4 has roller bearings 9 on either side of...

Contrary to Examiner's assertions, Paton only teaches that the window portion of the housing is a subassembly removable from the remainder of the housing along line 101 by loosening the Allen screws 100 shown in FIG. 1. (See column 2, line 61 - column 3, line 1.) Nowhere does Paton disclose a reservoir made from a plurality of separate pieces between which the scan window is mechanically secured. Examiner is respectfully requested to withdraw the rejection of claim 12.

In addition, Examiner erroneously states that Hayakawa discloses a cross-linked hydrogel with a mesh support structure. The feature cited by Examiner (FIG. 3A, element 60A) is described by Hayakawa at column 8, lines 33-35: "The coupling member 60 is provided with *a plurality of holes 60a* through which the gel material is inserted." and further at column 8, lines 60-63: "Therefore, a strong coupling force is obtained by integrated formation, in which the gel material passed through *holes 60a formed in the coupling member 60*." Applicant has diligently searched through 10

dictionaries and cannot find a definition of “mesh” that supports Examiner’s interpretation of the Hayakawa reference as disclosing a mesh support structure for the gel material. Accordingly, Examiner is respectfully requested to withdraw the statement.

5. Claims 2, 15 and 18 were rejected under 35 USC 103(a) as being unpatentable over Paton et al. (US 4,120,291) in view of Hayakawa et al. (US 5,575,291) and further in view of Katsumata (US 5,078,149).
6. Applicant respectfully traverses the rejection of claims 2, 15 and 18 under 35 USC 103(a) for the reasons stated above in connection with claims 1, 4, 6, 9, 12 and 19. As stated above, it would not be obvious to combine the Paton and Hayakawa references as suggested by the Examiner and, even if combined, the combination would not result in Applicant’s claimed invention because the suggested combination would be nonfunctional. Katsumata’s teaching of an ultrasonic coupling made of a polymeric gel that can be simultaneously crosslinked and sterilized by exposure to radiation does nothing to remedy the deficiencies of the proposed combination of references. Therefore, claims 2 and 18 are submitted as being patentable over the combination of Paton, Hayakawa and Katsumata under 35 USC 103(a).

Regarding claim 15, none of the cited references disclose the claimed feature “wherein the device incorporates access for surgical instruments.” Consequently, no possible combination of the references could result in Applicant’s claimed invention. Therefore, claim 15 is submitted as being patentable over the combination of Paton, Hayakawa and Katsumata under 35 USC 103(a).

7. Claim 8 was rejected under 35 USC 103(a) as being unpatentable over Paton et al. (US 4,120,291) in view of Hayakawa et al. (US 5,575,291) and further in view of Matthews (US 3,939,123).

8. Matthews relates to the production of fibrous materials for use as absorbents for moisture. (See column 1, lines 8-23.) The application of the disclosed materials for absorption of moisture is not analogous to the present application, which relates to the construction of an ultrasonic coupling for use in ultrasonic imaging during eye surgery. Thus, one of ordinary skill in the art would not look to Matthews for solutions to problems encountered in ultrasonic imaging for eye surgery. Furthermore, one of ordinary skill in the art would not look to Matthews because the objective of this reference is to produce a fibrous absorbent material and this form of material is unsuitable for use as a scan window, and is particularly unsuitable as a scan window for containing a fluid acoustic coupling medium within a reservoir.

Given that the material disclosed by Matthews is unsuitable for use as a scan window in an ultrasonic coupling, it was clearly only with the hindsight provided by Applicant's disclosure that Examiner found this reference to be relevant to Applicant's claims at all. In effect, Examiner went "shopping" for the claim limitation but only came up with a reference that is both nonanalogous and unsuitable for use in the claimed invention.

For all of these reasons, claim 8 is submitted as being patentable over the combination of Paton, Hayakawa and Matthews under 35 USC 103(a).

9. Claims 10 and 14 were rejected under 35 USC 103(a) as being unpatentable over Paton et al. (US 4,120,291) in view of Hayakawa et al. (US 5,575,291) and further in view of Puech (US 6,837,855).
10. Applicant respectfully traverses the rejection of claims 10 and 14 under 35 USC 103(a) for the reasons stated above in connection with claims 1, 4, 6, 9, 12 and 19. As stated above, it would not be obvious to combine the Paton and Hayakawa references as suggested by the Examiner and, even if combined, the combination would not result in Applicant's claimed invention because the suggested combination would be nonfunctional. Puech's disclosure contains nothing that would remedy the deficiencies

of the proposed combination of references.

Furthermore, regarding claim 10, neither Paton, Hayakawa nor Puech discloses "means for adjusting a distance between said scan window and the transducer to allow adjustment of a position of said scan window with respect to a focus of the transducer" as recited in claim 9, from which claim 10 depends. Consequently, no possible combination of the references could result in Applicant's claimed invention. Moreover, there is no overlap between the claimed range of 2 to 6 mm and the range of focal lengths disclosed by Puech. (See MPEP 2144.05 Obviousness of Ranges.) The section of the Puech reference cited by Examiner (column 6, lines 38-48) discloses two specific transducers with focal lengths of 7.5 mm and 12.5 mm. As there is no overlap with the claimed range of 2 to 6 mm, claim 10 is submitted as being patentable over the combination of Paton, Hayakawa and Puech under 35 USC 103(a).

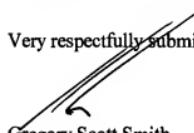
11. Claims 16 and 17 were rejected under 35 USC 103(a) as being unpatentable over Paton et al. (US 4,120,291) in view of Hayakawa et al. (US 5,575,291) and further in view of de Juan et al. (US 2001/0029335).
12. Applicant respectfully traverses the rejection of claims 16 and 17 under 35 USC 103(a) for the reasons stated above in connection with claims 1, 4, 6, 9, 12 and 19. As stated above, it would not be obvious to combine the Paton and Hayakawa references as suggested by the Examiner and, even if combined, the combination would not result in Applicant's claimed invention because the suggested combination would be nonfunctional. The disclosure of de Juan contains nothing that would remedy the deficiencies of the proposed combination of references. Therefore, claims 16 and 17 are submitted as being patentable over the combination of Paton, Hayakawa and de Juan under 35 USC 103(a).

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

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